K130479

510(k) Summary of Safety and Effectiveness

Ilizarov Drill Tip Wires

MAY 1 4 2013

Submitted By: Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

Date: May 10, 2013

Contact Person: David Henley, Regulatory Affairs Project Manager
Tel: (901) 399-6487 Fax: (901) 566-7079

Proprietary Name: **Ilizarov Drill Tip Wires**

Common Name: Multilateral Fixators and Accessories

Classification Name and Reference: 21 CFR 888.3030, single/multiple component metallic bone fixation appliance and accessories - Class II

Device Product Code and Panel Code: KTT / Orthopedics / 87

Device Description:

The subject **Ilizarov Drill Tip Wires** are comprised of implantable *anchorage elements* designed for use in a multilateral (i.e. a circular) *fixator assembly* comprised of a structurally purposeful arrangement of *simple* or *complex bridge elements*, *connection elements* and *anchorage elements*. The subject devices are manufactured from implant grade stainless steel material. Compared to the predicate devices, the subject devices will be available in the following configurations:

Device Type	Diameter	Length
Ilizarov Drill Tip Wire, 1.8mm x 400mm	1.8mm	400mm
Ilizarov Drill Tip Wire with Stopper, 1.8mm x 400mm	1.8mm	400mm

Intended Use:

Ilizarov Drill Tip Wires are intended to be used for the following indications:

Post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; open and closed fracture fixation; pseudoarthrosis of long bones; limb lengthening by epiphyseal or metaphyseal distraction; correction of bony or soft tissue deformities; correction of bony or soft tissue defects; joint arthrodesis; and infected fractures or nonunions.

Ilizarov Drill Tip Wires are for single use only.

Technological Characteristics:

Ilizarov Drill Tip Wires are very similar to legally marketed predicate devices listed below in that they share identical or very similar indications for use, are manufactured from stainless steel material and incorporate identical or very similar technological design characteristics.

Substantial Equivalence Information:

When compared to the predicate devices listed below, substantial equivalence is based on identical or very similar design features, overall indications for use, and raw material composition.

- Smith & Nephew Smooth and Olive Wires – K994143
- Ilizarov Drill Tip Wires – K093047
- Richards Transfixation Wires – K870961
- Smith & Nephew Drill Tip Kirschner Wires (K-wires) – K090675
- Ilizarov External Fixation System – Titanium Wires and Washers – K962808

Preclinical Testing:

To further support a determination of substantial equivalence, pre-clinical bench testing was conducted on the subject **Ilizarov Drill Tip Wires.** Mechanical test results were compared against predicate devices. The specific type of pre-clinical testing conducted is described as:

- Cutting performance of the wire including: *number of start/stops prior until failure, time to insertion and insertion temperature*

Conclusion:

Based on similarities in design and on the results of mechanical testing, the subject device is substantially equivalent to predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Smith and Nephew, Incorporated
% Mr. David Henley
Regulatory Affairs Project Manager
1450 Brooks Road
Memphis, Tennessee 38116

Letter dated: May 14, 2013

Re: K130479
Trade/Device Name: Ilizarov Drill Tip Wires
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: March 15, 2013
Received: March 18, 2013

Dear Mr. Henley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification

Indications for Use Statement

510(k) Number (if known): K130479

Device Name: Ilizarov Drill Tip Wires

Indications for Use:

Ilizarov Drill Tip Wires are intended to be used for the following indications:

- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Open and closed fracture fixation
- Pseudoarthrosis of long bones
- Limb lengthening by epiphyseal or metaphyseal distraction
- Correction of bony or soft tissue deformities
- Correction of bony or soft tissue defects
- Joint arthrodesis
- Infected fractures or nonunions

Ilizarov Drill Tip Wires are for single use only.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices